

MAY 31 2005 510(k) SUMMARY

SMITH & NEPHEW PATELLO-FEMORAL KNEE IMPLANT

SUBMITTER'S NAME:	Smith & Nephew, Inc., Orthopaedic Division
SUBMITTER'S ADDRESS:	1450 Brooks Road, Memphis, TN 38116
SUBMITTER'S TELEPHONE NUMBER:	901-399-6707
CONTACT PERSON:	Gino J. Rouss
DATE SUMMARY PREPARED:	April 26, 2005
TRADE OR PROPRIETARY DEVICE NAME:	Smith & Nephew Patello-Femoral Implant
COMMON OR USUAL NAME:	Patello-Femoral Replacement
CLASSIFICATION NAME:	Knee joint patellofemoral polymer/metal semi-constrained cemented prosthesis
DEVICE CLASS:	Class II
PANEL CODE:	Orthopedics/87 KRR

DEVICE INFORMATION:**A. INTENDED USE:**

The Smith & Nephew Patello-Femoral Implant is indicated for replacement of the femoral side of the patello-femoral joint. It is intended to be used in patellofemoral arthroplasty in patients with degenerative arthritis in the distal femur and patella, patients with a history of patellar dislocation or patellar fracture, and patients with failed previous surgery (arthroplasty, tibial tubercle elevation, and lateral release) where pain, deformity or dysfunction persists. The components are for single use only and are intended for implantation with bone cement.

These indications are the same as found with the Howmedica Osteonics Avon™ Patello-Femoral Joint Prosthesis cleared via K010100 and K041160.

B. DEVICE DESCRIPTION:

The Smith & Nephew Patello-Femoral Components are intended to replace the patellofemoral articulating surface of the femur. The components will be manufactured from Oxinium and will be initially manufactured in sizes x-small, small, medium, and large. Each size will be provided in both left and right configurations. The trochlear groove geometry is the same geometry as found with the Smith & Nephew Genesis II Total Knee Femoral Component subject of K951987.

C. SUBSTANTIAL EQUIVALENCE INFORMATION:

The Smith & Nephew Patello-Femoral Components are similar to the following commercially available devices regarding design features, overall indications, and materials:

- Smith & Nephew (formerly Richards Medical) Patella Type 1 (preamendment)
- Howmedica Osteonics Corporation Avon™ Patello-Femoral Joint Prosthesis (K010100 and K041160)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 31 2005

Mr. Gino J. Rouss, M.S.
Regulatory Affairs Specialist
Smith & Nephew Incorporated
Orthopaedic Division
1450 E. Brooks Road
Memphis, Tennessee 38116

Re: K051086

Trade/Device Name: Smith & Nephew Patello-Femoral Knee Implant
Regulation Number: 21 CFR 888.3540
Regulation Name: Knee joint patellofemoral polymer/metal semi-constrained cemented
prosthesis
Regulatory Class: II
Product Code: KRR
Dated: April 26, 2005
Received: April 28, 2005

Dear Mr. Rouss:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

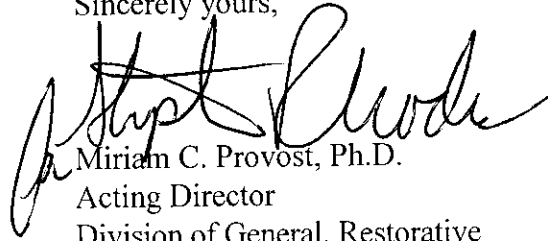
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Mr. Gino J. Rouss, M.S.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Miriam C. Provost", is written over the typed name.

Miriam C. Provost, Ph.D.

Acting Director

Division of General, Restorative
and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

K051086

Indications for Use

510(k) Number (if known):

Device Name: Smith & Nephew Patello-Femoral Knee Implant

Indications for Use:

The Smith & Nephew Patello-Femoral Implant is indicated for replacement of the femoral side of the patello-femoral joint. It is intended to be used in patellofemoral arthroplasty in patients with:

1. Degenerative arthritis in the distal femur and patella.
2. A history of patellar dislocation or patellar fracture.
3. Failed previous surgery (arthroplasty, tibial tubercle elevation, lateral release) where pain, deformity or dysfunction persists.

The Smith & Nephew Patello-Femoral Implants are for single use only and are intended for implantation with bone cement.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**

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